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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,747	04/18/2005	Peggy E. Hellberg	2395 US F	3474

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Alcon Research
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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	PAPER NUMBER
1612	
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08/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,747	HELLBERG, PEGGY E.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3* is/are pending in the application.

4a) Of the above claim(s) *3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed May 10, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claim 1 has been amended.

2. Claims 1 and 3 are pending in the case.

3. Claim 1 is present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

6. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao (U.S. Pat. 7250514) in view of Clark et al. (U.S. Pat. 5464866).

Xiao teaches the use of particular histone deacetylase inhibitors including suberoylanilidine hydroxamic acid, to treat conditions with abnormal angiogenesis and

neovascularization including diabetic retinopathy and neovascular glaucoma (Abstract, Col. 3 line 1-Col. 4 line 36, Col. 14, line 8-Col. 15 line13, Col. 29 lines 49-65, Col. 30 line 19).

Xiao does not expressly teach the use of the histone deacetylase for primary open glaucoma (also known in the art as chronic glaucoma as evidenced by Medline, Heiting et al., and Patient UK sheets) but does teach its ophthalmological use for conditions with abnormal angiogenesis and neovascularization including diabetic retinopathy and neovascular glaucoma.

Clark et al. teaches that a compound affecting neovascularization can treat the following ocular neovascular conditions including diabetic retinopathy, neovascular glaucoma, and chronic glaucoma (Col. 7 line 34-63).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the histone deacetylase inhibitors such as suberoylanilidine hydroxamic acid for chronic glaucoma, as suggested by Clark et al., and produce the instant invention. It would have been obvious to one of skill in the art as Xiao teaches that the compounds (e.g. SAHA) treat abnormal angiogenesis and neovascularization such as diabetic retinopathy and neovascular glaucoma; Clark teaches that treatment of neovascular conditions of the eye includes diabetic retinopathy, chronic glaucoma, and neovascular glaucoma; and it would be obvious to one of skill in the art use the histone deacetylase inhibitors which treats neovascular conditions and names diabetic retinopathy and neovascular glaucoma, to treat other related neovascular conditions of the eye such as chronic glaucoma as addressed by

the art. It is noted that to treat a patient for a specific condition, one would implicitly have been diagnosed with the condition.

One of ordinary skill in the art would have been motivated to do this because it is desirable to treat as many neovascular conditions as possible and it is desirable to be able to treat as many patient populations as possible with the same compound.

Double Patenting

8. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 12/609873. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the instant claim anticipate the copending claim 1 and the same compounds of the instant claim are present and claimed in the copending claim 2 for treatment of the same claimed condition primary open angle glaucoma (chronic glaucoma) which is also claimed in the copending application with other ocular neovascular conditions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao (U.S. Pat. 7250514) in view of Clark et al. (U.S. Pat. 5464866).

Applicant's arguments filed 5/10/2010 have been fully considered but they are not persuasive. Applicant addresses that the various types of chronic glaucoma are not identical and not with the same pathophysiology citing that neovascular glaucoma and

primary open angle glaucoma are not the same diseases. This is not persuasive and slightly confusing. The rejection addresses diabetic retinopathy, neovascular glaucoma, and chronic glaucoma as three conditions that can be treated by the same compound which is useful for addressing neovascularization. Neovascular glaucoma is not addressed as chronic glaucoma as it appears to be indicated by Applicant. The neovascular glaucoma and chronic glaucoma are separate conditions but are addressed to be treatable with the same drug, whereby a drug that is useful for treating neovascular conditions such as diabetic retinopathy and neovascular glaucoma would obviously be utilized for chronic glaucoma.

Applicant also asserts that chronic glaucoma is not primary open angle glaucoma (POAG) but that primary open angle glaucoma is a subset of chronic glaucoma. This is not persuasive as chronic glaucoma is known in the art to be open angle glaucoma or POAG which is the most common glaucoma as evidenced by Heiting et al. (Types of Glaucoma: "The two major types of glaucoma are chronic or primary open-angle glaucoma (POAG) and acute angle-closure glaucoma."), Patient UK (Chronic Open Angle Glaucoma: What is glaucoma? -"Chronic open angle glaucoma (also called chronic glaucoma or primary open angle glaucoma) is the most common type."), and MedlinePlus from the U.S. National Library of Medicine and National Institutes of Health (Glaucoma: Causes-"Open-angle (chronic) glaucoma is the most common type of glaucoma."). Additionally, even if POAG where to be viewed as a subset of chronic glaucoma contrary to what is acknowledged in the art, treatment of chronic glaucoma

with a drug would be useful for the treatment of the glaucoma subsets (e.g. POAG) comprising chronic glaucoma absent evidence to the contrary.

As for the assertion that that the ability of a compound to treat both neovascular glaucoma and POAG is unusual and compounds such as carbonic anhydrase inhibitor (CAI) are commonly prescribed to treat POAG but are not useful for directly affecting neovascular glaucoma and referring to Mabuchi et al. for failure of CAI's and anti-glaucoma eye drops to treat the neovascular glaucoma leading to laser treatment is fully considered but not persuasive as this is not accurate. A drug useful for the treatment of a condition does not mean that every patient will be responsive to the drug which is why there is more than one drug per type of drug category and different drugs are used on patients to find which ones are efficacious for that particular patient. As for Mabuchi, it is directed to the efficacy of a particular type of procedure for neovascular glaucoma, not about efficacy of drug treatment. Additionally, the CAI utilized is acetazolamide and the assertion that CAI's are useful for POAG but not neovascular glaucoma is not persuasive as CAI's such as dorzolamide which are known for treating POAG, are also useful for neovascular glaucoma as evidenced by Hagiwara et al. which is published after Mabuchi wherein a compound known to be useful for one form of glaucoma (e.g. POAG) is also useful for another (neovascular glaucoma).

Accordingly, the rejection is maintained.

10. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/697135.

There are no arguments.

Accordingly, the rejection is maintained.

Conclusion

11. Claim 1 is rejected.

12. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/
Examiner, Art Unit 1612
/Zohreh A Fay/
Primary Examiner, Art Unit 1612